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Remarks

This Supplemental Preliminary Amendment is being filed after filing of the above identified application and prior to receipt of an office action on the merits.

A Petition to Make Special based on infringement was filed with the application on April 21, 2006. A Preliminary Amendment was also filed with the application on April 21, 2006.

A Notice of Acceptance of Application under 35 U.S.C 371 was mailed on January 23, 2007, indicating that the preliminary amendment was not entered because of improper format for entry. (A copy of the Notice of Acceptance is filed herewith for the sake of convenience).

The Petition to Make Special was granted on March 6, 2007.

The undersigned attorney of record spoke with Examiner Isis Ghali on even date herewith, i.e. March 27, 2007. The Examiner pointed out that the original preliminary amendment filed on April 21, 2006 had not been entered due to incorrect claim numbering. The Examiner indicated that the claims could be amended prior to examination of the application upon filing of a Supplemental Preliminary Amendment with correct claim numbering. Accordingly, the present Supplemental Preliminary Amendment is being filed, and respectfully requests entry of thereof prior to examination of the application.

Claims 1 to 32 and claims 34, 37, 40, 42, 43 and 46-54 are cancelled without prejudice. Claim 33 has been amended. New

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claims 55-66 have been added. Applicant expressly reserves the right to seek patent protection for the original claims and for all other claims supported by the above-identified application, for example, in one or more related applications. No new matter is being added by this amendment.

Amended claim 33 is directed to a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes.

New claim 55 is directed to a method of treating hot flashes associated with menopause in a woman, the method comprising placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel.

New claim 61 is directed to a method of treating hot flashes associated with menopause in a woman, the method comprising the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes.

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DETAILED DISCUSSION OF THE REFERENCES  
AND HOW THE CLAIMS ARE PATENTABLE  
OVER THE REFERENCES

Applicant now provides a detailed discussion of the references deemed most closely related to the subject matter encompassed by the claims and a discussion of how the claimed subject matter is patentable over the references. A copy of each of the references is enclosed.

Yanagibashi et al., U.S. Patent No. 4,900,554

Yanagibashi et al. discloses an adhesive device for application to body tissue such as the oral cavity. The device provides sustained drug release to such body tissue or is used to protect such body tissue. The device has an adhesive layer and a backing layer positioned over one side of the adhesive layer. The adhesive layer includes one or more acrylic acid polymers having adhesive properties upon dissolution or swelling in water, and at least one water insoluble cellulose derivative. The backing layer is water insoluble or sparingly water soluble.

Yanagibashi et al. does not disclose, teach, or suggest the present invention. For example, Yanagibashi et al. does not disclose, teach, or even suggest a method of treating hot flashes. Yanagibashi et al. does not teach providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is

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experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, Yanagibashi et al. does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

In addition, Yanagibashi et al. does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over Yanagibashi et al. under 35 U.S.C. 102(b) and 103(a).

Kamiya et al., U.S. Patent No. 5,780,047

Kamiya et al. discloses a patch that comprises a water-soluble adhesive sheet, and a water-soluble protective material laminated thereon. The patch can be applied to the skin so as to exhibit warm-bathing effects on the application site.

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Kamiya et al. does not disclose, teach, or suggest the present invention. For example, Kamiya et al. does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, Kamiya et al. does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

In addition, Kamiya et al. does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

Kamiya et al.'s patch for exhibiting warm-bathing effects clearly teaches away from the present methods which are directed to cooling, not warming.

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In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over Kamiya et al. under 35 U.S.C. 102(b) and 103(a).

Misumi et al., U.S. Patent Nos. 6,224,899; 6,228,376; and  
6,524,612

Each one of the Misumi et al. patents discloses an adhesive cooling gel composition which contains water and which provides a cooling effect and/or coolness-preserving effect. Also disclosed is an adhesive cooling composition shaped into a sheet, and a process for preparing the adhesive cooling composition. The Misumi et al patents disclose that the adhesive cooling composition can be applied to the forehead of a subject which is feverish, and can be used to cool eyes, cheeks, jaws and feet, or can cool inflammatory parts to assuage the pain when suffering from blow pain, sprain or muscular pain.

The Misumi et al. patents do not disclose, teach or suggest the present invention. For example, Misumi et al. do not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman. Moreover, the Mitsumi et al patents do not disclose, teach or even suggest providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman, as recited in amended claim 33.

Further, the Misumi et al. patents do not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at

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least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

In addition, the Misumi et al. patents do not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over each of the Misumi et al. patents under 35 U.S.C. 102(b) and 103(a)..

Lerner, U.S. Patent No. 5,956,963

Lerner discloses a wrist cooler that offers relief for hot flash symptoms of menopause and body overheating. The cooler includes chemical cooling pellets that remain in a solid state until broken. A woman experiencing one or more symptoms of menopausal hot flashes carries the cooler in her purse. When a hot flash occurs, the cooler is removed from her purse, the pellets are broken and the cooler is slid onto her wrist. Once the flash has subsided, the cooler is removed from the wrist and is discarded.

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Lerner does not disclose, teach or suggest the present invention. For example, Lerner does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, Lerner does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

In addition, Learner does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

Applicant submits that Lerner teaches away from the present invention in that the Lerner device is specifically designed and intended to be placed around the wrist, and not on the back, of the woman.



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In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over Lerner under 35 U.S.C. 102(b) and 103(a).

Cummings et al. U.S. Pat. No. 6,692,763

Cummings et al. discloses methods for treating a postmenopausal woman using a transdermal drug delivery patch to provide low doses of estrogen to the woman. The method comprises administering to the woman, an amount of estrogen which is effective to produce in the woman a target serum estradiol level.

Cummings et al does not disclose, teach or suggest the present invention. For example, Cummings et al does not disclose, teach, or even suggest a method of treating hot flashes in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, Cummings et al does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

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In addition, Cummings et al does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

Applicant submits that Cummings et al teaches away from the present invention in that Cummings et al does not disclose providing a cooling device for treating hot flashes, but teaches the use of a transdermal drug delivery patch for treating a postmenopausal woman.

Patterson, U.S. Patent Publication No. 2003/0176904

Patterson discloses a self-adhering cotton fabric cold strip that is to be worn as a wrist band or an ankle band. The self-adhering cotton fabric cold strip has an envelope defining a sealed cold strip volume. A cooling gelatinous material is positioned in the cold strip volume. A bandage sheet is fixed to the envelope. The bandage sheet defines a bandage adhesive for temporary adhesion of the cold strip to the skin surface of a user. The self-adhesive envelope contains a cooling gelatinous material which reduces the body temperature. The cold strip is to be worn as a wrist or ankle band.

Patterson does not disclose, teach or suggest the present invention. For example, Patterson does not disclose, teach, or even suggest a method of treating hot flashes associated with

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menopause in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, Patterson does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

In addition, Patterson does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

Applicant further submits that Patterson actually teaches away from the present invention in that Patterson specifies placing a cold strip on the wrist or ankle of a user, not placing a cold strip on the back of the user.

In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over Patterson under 35 U.S.C. 102(b) and 103(a).

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Product Concept Test Presentation

Product Concept Test Presentation, hereinafter, "Presentation", prepared for Kobayashi Healthcare, Inc., dated August 14, 2003, and was received on a private, non-confidential basis by applicant's representative, on or about October 27, 2005, from representatives of Kobayahsi Healthcare, Inc., assignee of the Misumi et al. patents referenced above. The Presentation discloses a consumer opinion research report which was conducted for Kobayashi Healthcare, Inc. A portion of the report discloses Cooling Gel Sheets for Hot Flashes and Cooling Pads for Adults.

The Presentation does not disclose, teach or suggest the present invention. For example, The Presentation does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device and instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in amended claim 33.

Further, the Presentation does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, wherein the cooling device comprises a water-containing gel, as recited in new claim 55.

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In addition, the Presentation does not disclose, teach or suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on the back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in new claim 61.

The Presentation provides no indication of the manner in which the Cooling Sheets for Hot Flashes or Cooling Pads for Adults are used.

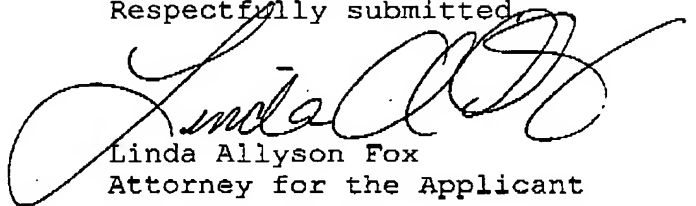
In view of the above, applicant submits the present claims are not anticipated by and are unobvious from and patentable over the Presentation under 35 U.S.C. 102(b) and 103(a).

In addition, applicant submits that no combination of Yanagibashi et al., Kamiya et al., Misumi et al., Lerner, Cummings, Patterson and/or the Presentation makes the present invention obvious. For example, none of the references taken alone or in any combination even suggests a method of treating hot flashes as recited in the present claims.

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Applicant respectfully requests early and favorable action  
in the above identified application.

Respectfully submitted,



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